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Attorney for Plaintiff Farnum Alston

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BUTTE DIVISION**

FARNUM ALSTON)	
)	No. CV 17-81-BU-SEH
Plaintiff,)	
)	
vs.)	FIRST AMENDED COMPLAINT
)	AND JURY DEMAND
UNITED HEALTHCARE)	
SERVICES, INC., OPTUMRX)	
INC. AND JOHN/JANE DOES 1-)	
10)	
)	
Defendants.)	

COMES NOW the Plaintiff, FARNUM ALSTON, by and through
undersigned counsel, and hereby allege the following in support of his Complaint:

I. PARTIES

1. Plaintiff, Farnum Alston (“Alston”) is an individual who is a Montana citizen who resides in Bozeman, Montana.

2. Defendant United Healthcare Services, Inc. (“UHC”) is a corporation organized under the laws of the state of Delaware with a principal place of business in Minnetonka, Minnesota. UHC writes insurance policies for citizens of the state of Montana.

3. OptumRx, Inc. (“Optum”) is a corporation organized under the laws of the state of California with a registered office address in St. Paul, Minnesota. OptumRx does business in the state of Montana with Montana Citizens.

4. John/Jane Does 1-10 are pharmacists employed by UHC or OptumRx. John/Jane Does are citizens of states other than Montana.

II. JURISDICTION AND VENUE

5. Plaintiff realleges and incorporates paragraphs 1-4 as if set forth fully herein.

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. §____ because Plaintiff is a citizen of the State of Montana and none of the Defendants are citizens of the State of Montana. The amount in controversy exceeds \$75,000.

7. Venue is proper in this district because the events comprising this action and resulting in damage to Alston occurred in Montana.

III. BACKGROUND

8. Plaintiff realleges and incorporates paragraphs 1-6 as if set forth fully herein.

9. Alston is a 72-year-old man with type II diabetes and end-stage renal disease. However, he has not allowed these medical conditions to curtail his lifestyle. In the past five years, he has travelled to Nepal several times to bring relief supplies to Mt. Everest base camps. His activities in this regard are very important to him.

10. Due to his diabetes, Alston is susceptible to wound infections and diabetic ulcers, particularly on his feet. A number of these infections were caused by antibiotic-resistant bacteria. When such an infection occurs, it must be treated promptly and aggressively. Sepsis and osteomyelitis are particular risks associated with these infections.

11. Alston purchased a Medicare supplemental prescription insurance policy from UHC that had been endorsed by AARP. OptumRx is a prescription management and “Specialty Pharmacy” organization that manages Medicare Part D benefits to Alston.

A. Industry standards UHC and OptumRx should have followed.

12. Plaintiff realleges and incorporates paragraphs 1-10 as if set forth fully herein.

13. According to the Centers for Medicare and Medicaid Services (CMS), to be considered "specialty," a drug must fall into five of the following eight categories:

- a. Treats specific, mainly chronic, and often rare conditions;
- b. Usage initiates with a specialist;
- c. Typically, not administered orally;
- d. Requires special handling;
- e. Involves unique distribution and administration channels, such as special distribution management and specialized paperwork;
- f. Is costly, ranging from \$6,000-\$750,000 per year;
- g. Requires high degrees of patient management, like increased supervision of counseling; and
- h. Results in patients requiring reimbursement assistance.

14. According to leading Drug Formulary company Caremark, Zyvox is a specialty drug. The AARP MedicareRx Preferred (PDP) lists Zyvox as a "Tier 5: Specialty tier" drug, and the 2014 Medicare Part D and Medicare Advantage Plan Formulary Browser also lists Zyvox as a Tier 5 specialty drug

15. The specialty pharmacy market is fueled by the increasing number of complex chronic conditions that require the latest highly engineered pharmaceuticals.¹ Therefore, according to industry best practices and guidelines, so called “Specialty Pharmacies” are intended to offer a “...high-touch, comprehensive care system of pharmacological care wherein patients with chronic illnesses and complex disease states receive expert therapy management and support tailored to their individual needs.” Medications that health plans and other payers classify as specialty pharmaceuticals may vary and evolve over time.

16. URAC, an independent, nonprofit organization, is well-known as a leader in promoting health care quality through its accreditation, education and measurement programs. URAC offers a wide range of quality benchmarking programs and services that keep pace with the rapid changes in the health care system, and provide a symbol of excellence for organizations to validate their commitment to quality and accountability. Through its broad-based governance structure and an inclusive standards development process, URAC ensures that all stakeholders are represented in establishing meaningful quality measures for the entire health care industry.

¹ Pharmacy Specialty Times, 2012. Source document accessed October 2, 2017.
<https://www.specialtypharmacytimes.com/news/uracs-specialty-pharmacy-accreditation-incorporates-best-practices-for-treating-chronic-conditions>

17. URAC developed a specialty pharmacy accreditation program because it is one of the key distribution channels for pharmacy benefit management, and it extends URAC's consumer protection and empowerment efforts in managed care pharmacy.²

18. URAC provides an accreditation program for Specialty Pharmacies which includes five modules: Core Organizational Quality Standards; Customer Service, Communications and Disclosure Standards; Specialty Drug Management Standards; Pharmacy Operations Standards and Patient Management.

19. OptumRx is certified by URAC as a "Specialty Pharmacy," (See United Health Group's October 18, 2012 press release "OptumRx Awarded Platinum Honors by URAC for Best Practices..." October 18, 2012), and Pharmacy Specialty Times news article (See URAC's Specialty Pharmacy Accreditation Incorporates Best Practices for Treating Chronic Conditions" Wednesday April 25, 2012.

20. Industry best practices as outlined by URAC and voluntarily agreed to by UHC and OptumRx require urgent prior-approval coverage decisions to be made on a timely basis and if coverage is denied, to process appeals on a timely

² Pharmacy Specialty Times, 2012. Source document accessed October 2, 2017.
<https://www.specialtypharmacytimes.com/news/uracs-specialty-pharmacy-accreditation-incorporates-best-practices-for-treating-chronic-conditions>

basis. Specifically, the URAC best practices for an expedited Review Process states: “The organization provides for an expedited review process that:

- a. Is available in cases for which the time frame for completion of a non-expedited review would seriously jeopardize:
 - i. The life or health of the covered person; or
 - ii. The covered person’s ability to regain maximum function; and
- b. Includes written policies and/or documented procedures for: [--]
 - i. Acting upon expedited cases received and/or processed after hours; and
 - ii. Issuing a determination in writing within forty-eight (48) hours after the date of providing notice, if that initial notice was not provided in writing.”

21. URAC states “When processing a case regarding medical necessity and appropriateness, the organization and its reviewer(s) consider information pertinent to the case that will include the following as available, unless otherwise prohibited by state or federal law or regulation:

- a. The covered person’s medical records;
- b. The attending provider’s recommendation;
- c. The terms of coverage under the covered person’s health benefit plan;

- d. Information accumulated regarding the case prior to its referral for review, including rationale for prior review determinations.”
- e. Information submitted to the organization by the referring entity, covered person, or attending provider;
- f. Clinical review criteria and/or medical policy developed and used by the insurance issuer or group health plan; and
- g. Medical or scientific evidence. [3]”

22. According to the American Medical Association Journal of Ethics, under the Patient Protection and Affordable Care Act, “*Health plans are prohibited from requiring prior authorization for emergency services*, regardless of whether the clinician is in or out of network. Health plans must pay for out-of-network emergency services at either the in-network amount, the amount for other out-of-network services, or the amount that Medicare pays.” (See Patient Protection and Affordable Care Act; requirements for group health plans and health insurance issuers under the Patient Protection and Affordable Care Act relating to preexisting condition exclusions, lifetime and annual limits, rescissions, and patient protections; final rule and proposed rule. Fed Register. 2010;75(123):37187-37241. Codified at 29 CFR sec 2590.715-2719A. and Patient Protection and Affordable Care Act; requirements for group health plans. Codified at 45 CFR sec 147.138.) (emphasis added).

23. Industry best practices and guidelines according to the Journal of Managed Care Pharmacy clearly state a 24 hour review period. “To obtain a PA, the physician or his or her staff contacts the research site HMO. Requests should be reviewed within 24 hours of receipt. If the request fails to meet the research site HMO-approved criteria, a medical director reviews the request, relying upon accepted clinical and state guidelines. Arrangements are made for the patient to continue on therapy until the request is resolved.”³

B. Previous infections in 2013 and 2014 take parts of Alston’s right foot.

24. Plaintiff realleges and incorporates paragraphs 1-23 as if set forth fully herein.

25. In June 2013, Alston’s right great toe became infected. After trying a conservative course of action, i.e. antibiotic treatment, the wound failed to heal. Alston’s doctors did not prescribe Zyvox for this wound.

26. As of July 3, 2013, Alston had exposed bone on his toe. In consultation with his doctors, Dr. Jon Robinson, an orthopedic surgeon, Dr. Eric Johnson, who practices in the Bozeman Health wound clinic in Bozeman, Montana, and Dr. Mark Winton, a board-certified infections disease specialist,

³ <http://www.amcp.org/data/jmcp/Research-36-44.pdf>

Alston decided that surgical intervention was necessary and proceeded to have his right great toe amputated on July 9, 2013.

27. In August 2014, Alston developed a diabetic ulcer on his fourth right toe for which he promptly sought medical attention. Dr. Robinson discovered a large hawthorn thorn between the right fourth toe and the small toe that subsequently became infected with what cultures proved to be methicillin resistant staphylococcus bacteria.

28. Alston's doctors became alarmed that the wound did not respond to traditional antibiotics. Concerned that the infection would spread and become septic, Alston's doctors prescribed a highly-potent antibiotic called Zyvox, produced by the drug manufacturer Pfizer.

29. Zyvox is an antibiotic used for the treatment of infections caused by Gram-positive bacteria that are resistant to other antibiotics. Zyvox is active against most Gram-positive bacteria that cause disease, including streptococci, vancomycin-resistant enterococci (VRE), and methicillin-resistant Staphylococcus aureus (MRSA). The main uses are infections of the skin and pneumonia, although it may be used for a variety of other infections including drug resistant tuberculosis. It is used either by injection into a vein or by mouth. Zyvox is a member of the oxazolidinone class of medications.

30. When given for short periods, Zyvox is a relatively safe antibiotic. *It can be used in people of all ages and in people with liver disease or poor kidney function.*

31. As a protein synthesis inhibitor, Zyvox affects the ability of bacteria to produce protein. This either stops growth or results in bacterial death. Although many antibiotics work this way, the exact mechanism of action of Zyvox appears to be unique in that it blocks the start of protein production, rather than one of the later steps. As of 2014 bacterial resistance to Zyvox has remained low.

32. On information and belief, UHC and OptumRx required prior authorization before they would cover the cost Zyvox in 2014.

33. On information and belief, kidney disease is a factor that would indicate Zyvox would be covered by the insurance policy Alston purchased.

34. On information and belief, diabetes is a factor that would indicate Zyvox would be covered by the insurance policy Alston purchased.

35. OptumRx and UCH knew that Alston had kidney disease and diabetes based on the health records they possessed and the prescription medication he was taking.

36. Alston and his doctors requested prior approval for Zyvox on an *expedited basis* to cure Alston's infection.

37. In spite of the emergency, expedited request for Zyvox, UHC and OptumRx did not respond immediately. Several days after the request, UHC and OptumRx declined to cover Zyvox for Alston, in spite of the presence of two factors favoring coverage.

38. On information and belief, UHC and OptumRx did not review Alston's records that were in their possession before they denied coverage. On information and belief, a pharmacist recommended denial of the claim for Zyvox.

39. Alston's physicians determined that the next course of action would be to apply to Zyvox's manufacturer, Pfizer's Zyvox Assist program. To be eligible for Zyvox Assist, Alston had to submit the claim to UHC and OptumRx and they must have rejected the claim.

40. Based on Alston's Zyvox Assist application, Pfizer immediately approved Alston's request for Zyvox and he was able to get the much-needed medication.

41. The several-day delay between the request for prior approval and the initiation of the Zyvox treatment allowed the resistant bacteria to spread from the soft tissue to the bone of Alston's foot.

42. Once the infection entered the bone, the only treatment option was to amputate the afflicted area. Alston consequently lost a portion of his right foot, and subsequent to that another operation was needed to remove Alston's fourth toe,

which had become compromised by the aggressive infection and the delay in getting the prescribed Zyvox.

43. Extensive follow-up treatments were necessary to effect proper wound healing. These treatments included the use of Epfix, Grafix and hyperbaric treatment for nearly a year after the initial infection.

C. The 2015 infection causes Alston to lose his left great toe.

44. Plaintiff realleges and incorporates paragraphs 1-42 as if set forth fully herein.

45. In the late spring of 2015, Alston and Dr. Johnson were part of an expedition to bring medical relief supplies to the Mt. Everest base camps. On the return trip from the base camp at 18,000 feet in elevation, Alston developed a sore on his left great toe, often called “boot bang.”

46. Dr. Johnson, knowing that Alston had a severe infection in 2014 that resulted in an amputation, treated the wound on the way down the mountain. By all appearances, his treatments on the mountain and follow-up treatments at the Bozeman Health Wound Clinic were successful and the wound healed.

47. In October, 2015, the wound on Alston’s left great toe reappeared. Dr. Johnson and Dr. Winton began treatment.

48. Drs. Johnson and Winton recognized the signs of a resistant strain of bacteria in Alston’s wound. An x-ray taken on October 13, 2015 showed signs of

degeneration suspicious for osteomyelitis in the first distal phalanx. Further, the x-ray showed “[p]ossible infectious synovitis of the first interphalgeal joint *without apparent osteomyelitis in the first proximal phalanx.*” (emphasis added).

49. On this basis and because of Alston’s previous infection with a resistant bacterium, they immediately prescribed Zyvox on October 13, 2015 and requested prior approval from UHC and OptumRx. In anticipation of UHC’s and OptumRx’s expected denial of coverage, Dr. Johnson prepared the Zyvox Assist application. The form indicates that the medication was needed by October 14, 2015.

50. If UHC and OptumRx decided to cover the drug, then Alston could get the necessary therapy. If they decided not to cover the drug, then Alston could again obtain Zyvox through the Zyvox Assist program. *All Alston needed was for UHC and OptumRx to make a timely decision,* otherwise the infection would spread and could infect his bone, lead to sepsis or even death.

51. Between October 13, 2015 and October 16, 2015, Alston’s pharmacist, Drs. Jonhson’s and Winton’s offices and Alston himself made daily phone calls to UHC and OptumRx requesting a decision about whether they would cover the Zyvox.

52. Defendants did not respond on October 13.

53. Defendants did not respond on October 14.

54. Defendants did not respond on October 15.

55. While waiting for Defendants to respond, Alston received daily intravenous antibiotics through a port that injected the medicine directly into his heart to try to hold the infection at bay. This therapy was not curative, however and was intended to buy time while waiting for UHC and OptumRx to make a decision on coverage. Alston needed Zyvox.

56. In spite of daily calls by the pharmacist, the doctors' offices and Alston, *Defendants had not responded*. On Friday, October 16, 2015, Dr. Johnson's office made a second request for prior approval at approximately 3:18 p.m. The medical staff waited for a response from Defendants. After several hours with no response, they went home for the weekend.

57. At approximately 7:00 p.m. on Friday, October 16, after everyone had gone home for the weekend, Defendants faxed their notice of rejection to Dr. Johnson's office.

58. Alston's wound continued to get worse and more painful over the weekend.

59. On information and belief, UHC and OptumRx neither investigated Alston's need for Zyvox nor consulted Alston's medical records that they had in their possession. On information and belief, a John/Jane Doe defendant made the

decision to deny coverage, overruling a wound care doctor and a board-certified infectious disease specialist.

60. UHC and OptumRx had documents in their possession that put them on notice that Alston was diabetic and had kidney disease, *both indicators that Zyvox is an appropriate therapy and that it should be covered.* On information and belief, John/Jane Doe defendants had access to these documents.

61. UCH and OptumRx had documents in their possession that put them on notice that Alston had an antibiotic-resistant infection in 2014. On information and belief, John/Jane Doe defendants had access to these documents.

62. UHC, OptumRx and John/Jane Doe defendants knew or should have known that time was of the essence and that Alston could suffer dire, permanent and disfiguring consequences, even death, if he could not obtain immediate treatment with Zyvox.

63. UHC, OptumRx and John/Jane Doe defendants knew or should have known that the notice of denial of coverage at 7:00 p.m. on a Friday evening would not be read until Monday, October 19, 2015.

64. Upon receipt of UHC's and Optum's denial of coverage, Alston's doctors applied to the Zyvox Assist program through Pfizer. Pfizer immediately approved the application.

65. Alston began Zyvox therapy on Tuesday, October 20, 2015 – one full week after the initial, urgent request for prior approval, which, according to Defendants' own guidelines, should have been covered.

66. In any event, Defendants' delay in issuing a decision – any decision – prevented Alston from getting Zyvox from another source.

67. An MRI taken on October 27, 2015 revealed that, "The extent of bony destruction appears progressed in comparison to the previous exam." Because Alston could not get the Zyvox on a timely basis, the infection on his left great toe penetrated the bone. In consultation with his doctors, Alston determined that he had no option but to have part of his left great toe amputated.

68. On November 11, 2015, Alston had surgery to remove the infected portion of his left foot, including part of his great toe.

D. The 2016 infection gets proper treatment.

69. Plaintiff realleges and incorporates paragraphs 1-68 as if set forth fully herein.

70. In April, 2016, Alston developed another resistant bacterial infection on his right foot.

71. Alston had some Zyvox left over from the previous infection and, on advice from his physicians, started taking it as soon as he began to see signs of infection. He immediately met with Doctors Johnson and Winton for wound care.

72. Doctors Johnson and Winton, realizing that Alston could lose even more body parts and that this virulent type of infection could again be life-threatening, immediately sought prior approval for Zyvox again. UHC and OptumRx initially denied the claim. However, this time Doctors Johnson and Winton informed UCH and OptumRx that they must consider Alston's prior medical history, i.e. that he had two prior infections treated with Zyvox, that he is diabetic, that he has kidney disease and that in the previous infections, he lost parts of both feet.

73. Upon consideration of Alston's prior medical history for the first time and *which was already in their possession and had been in their possession since Alston contracted with them for insurance coverage*, UHC and OptumRx determined that they would cover Zyvox for Alston this time. More importantly, they made the decision promptly.

74. On information and belief, a pharmacist, and not a medical doctor, made the decision on coverage for Alston's Zyvox therapy.

75. As a result of their timely decision, Alston started a course of Zyvox immediately. The infection responded to the Zyvox and cleared.

76. Alston did not have to have any other body parts amputated because this time UHC's and OptumRx's decision to cover the medication was timely.

77. If UHC and OptumRx had made coverage decisions for Zyvox for the first two infections on a timely basis under the circumstances, Alston would have had a good chance to keep his left great toe, parts of his right foot and his right fourth toe.

IV. CAUSES OF ACTION

A. Negligence.

78. Plaintiff realleges and incorporates paragraphs 1-77 as if set forth fully herein.

79. Upon receiving Alston's prior approval request, UHC, OptumRx and John/Jane Doe defendants had a duty to conduct a reasonable investigation based upon all available information.

80. UHC, OptumRx and John/Jane Doe defendants had a duty to render a coverage decision within a reasonable amount of time under the circumstances.

81. UHC, OptumRx and John/Jane Doe defendants had Alston's medical and prescription history in their possession and could have consulted it at the time they made a coverage decision for Zyvox in October 2015.

82. On information and belief, UHC, OptumRx and John/Jane Doe defendants did not consult Alston's medical and prescription history when they made a coverage decision for Zyvox in October 2015.

83. On information and belief, UHC and OptumRx relied on John/Jane Doe defendants to render a coverage decision which ultimately overruled Dr. Johnson, who practices in wound care, and Dr. Winton, who is a board-certified infectious disease specialist.

84. UHC, OptumRx and John/Jane Doe defendants knew or should have known that Alston's situation in October 2015 was an emergency because of the medication prescribed and the daily telephone calls to their representatives.

85. UHC, OptumRx and John/Jane Doe defendants failed to make a coverage decision that meets industry best practices and guidelines, and it failed to follow its own policies and procedures as attested to the industry accreditation organization URAC. This delay allowed the infection on Alston's foot to expand into the bone of his foot.

86. Alston required amputation of part of his foot because UHC, OptumRx and John/Jane Doe defendants breached their duty to conduct a reasonable investigation based on all available information and affirm or deny coverage within a reasonable time under the circumstances after the prior approval request.

87. This breach of duty was the proximate cause of the spread of the infection which caused the amputation of Alston's toe.

88. Alston suffered severe, permanent and disfiguring damages as a result.

89. In contrast, in April 2016, UHC and OptumRx conducted a reasonable investigation based on all available information and affirmed coverage within a reasonable time. Consequently, Alston did not require amputation of body parts.

B. Intentional/negligent infliction of emotional distress.

90. Plaintiff realleges and incorporates paragraphs 1-89 as if set forth fully herein.

91. Defendants acted with deliberate indifference to the high degree of harm that would befall Alston if an immediate decision was not made with respect to the prior approval request for Zyvox in October 2015.

92. UHC's and OptumRx's policy of having pharmacists make coverage decisions is evidence of their deliberate indifference.

93. As a result of Defendants' indifference, Alston had part of his left foot amputated.

94. Alston consequently suffers from severe emotional distress and mental anguish.

C. Professional negligence v. John/Jane Doe defendants.

95. Plaintiff realleges and incorporates paragraphs 1-94 as if set forth fully herein.

96. John/Jane Doe defendants have a duty to use the ordinary care and diligence usually exercised and possessed by members of the profession.

97. John/Jane Doe defendants failed to make a timely decision on coverage on a medication in a situation they knew of should have known was an emergency based on the type of medication prescribed and other information that was available to them and which they should have consulted.

98. John/Jane Doe defendants also overruled the advice of Alston's doctors, a wound care practitioner and a board-certified infectious disease specialist, and further breached their professional duty.

99. The breach of professional duty was a proximate cause of Alston's injury and Alston suffered severe, permanent and disfiguring damages as a result.

D. Respondeat superior.

100. Plaintiff realleges and incorporates paragraphs 1-99 as if set forth herein.

101. John/Jane Doe defendants were acting in the course and scope of their employment when their delay in acting and overruling doctors caused Alston's injuries.

102. UHC and OptumRx therefore have a duty to indemnify John/Jane Doe defendants under the doctrine of respondeat superior.

E. Breach of contract v. UHC and OptumRx.

103. Plaintiff realleges and incorporates paragraphs 1-102 as if set forth herein.

104. Alston purchased a health insurance policy from UHC, with OptumRx as a pharmacy management organization. Alston made premium payments on time.

105. Among the services contracted for were coverage for necessary medications and timely claims management.

106. UHC and OptumRx denied Alston's claim for Zyvox in October 2015 when they should have covered it, according to their own criteria.

107. UHC and OptumRx failed to handle Alston's claims in a timely manner, a benefit Alston had bargained for.

108. UHC and OptumRx thereby breached the insurance contract between them and Alston. Alston suffered the severe, permanent and disfiguring consequences from the breaches of the contract.

WHEREFORE, Plaintiff FARNUM ALSTON prays for the following relief:

- a) Judgment in his favor against Defendants United Healthcare Services, Inc., OptumRx Inc. and John/Jane Doe defendants;
- b) Compensatory damages in the amount of \$500,000.00
- c) Exemplary damages in an amount sufficient to deter the conduct complained of in this Complaint;
- d) Reasonable attorney's fees and costs of suit; and
- e) Such other relief this honorable court deems proper in the interest of justice.

DATED the 30th day of November, 2017

YOUNG LAW OFFICE PLLC

By: Christopher C. Young

WATSON LAW OFFICE P.C.

By: Herman A. Watson III

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury of all issues triable by jury.

RESPECTFULLY SUBMITTED this 30th day of November, 2017

YOUNG LAW OFFICE PLLC

/s/ Christopher C. Young
By: Christopher C. Young

WATSON LAW OFFICE P.C.

/s/ Herman A. Watson III
By: Herman A. Watson III

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of November, 2017 the foregoing First Amended Complaint was served on the following counsel of record by email and ECF:

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/s/ Christopher C. Young